SECTION 5. 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Name, Address, Phone and Fax Number of the Applicant

Thoratec Laboratories Corporation
Pleasanton, California 94588
(925) 847-8600
(925) 847-8628 fax

B. Contact Person

Donald A. Middlebrook
Vice President, Regulatory Affairs and Quality Assurance
6035 Stoneridge Drive
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C. Date Prepared

June 23, 2000

D. Device Name

Vectra™ Tunneler

E. Device Description

The *Vectra*™ Tunneler is a 3-piece device used to introduce and properly position the Thoratec *Vectra*™ graft. The three pieces include the tunneler shaft with handle, the tunneler sheath (hollow tube), and the tunneler "bullet tip". The fully assembled tunneler is intended to facilitate the implantation of either the 5 mm or 6 mm Thoratec *Vectra*™ graft. Each tunneler is supplied non-sterile in a box and must be

disassembled and sterilized prior to use. Each tunneler kit will also contain an extra tunneler sheath and a dissecting tip.

F. Device Intended Use

The *Vectra*™ Tunneler is indicated for use in creating subcutaneous tunnels for the placement of the Thoratec *Vectra*™ VAG for arteriovenous access.

G. Substantial Equivalence Summary

The *Vectra*™ Tunneler is substantially equivalent in design, materials and intended use to the Gore-Tex Tunneler (510(k)'s K844584 and K920998).

H. Device Testing

Physical testing was conducted to determine the strength characteristics of the *Vectra*™ Tunneler over its useful life. Additionally, the *Vectra*™ Tunnelers were utilized during clinical studies with the Thoratec *Vectra*™ graft. The results of all testing indicate that the *Vectra*™ Tunneler is suitable for use in the introduction and positioning of the Thoratec Vectra™ graft when used in accordance with it's Directions for Use. The results demonstrate that the *Vectra*™ Tunneler has been adequately designed to perform in a manner substantially equivalent to that of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 22 2000

THORATEC® Laboratories Corporation
c/o Mr. Rajagopal Kowligi, Ph.D.
Manager, Regulatory Affairs
6035 Stoneridge Drive
Pleasanton, CA 94588

Re: K001926
Trade Name: Thoratec *Vectra*™ Vascular Tunneler
Regulatory Class: II (two)
Product Code: DYB
Dated: June 23, 2000
Received: June 26, 2000

Dear Dr. Kowligi:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): To be Assigned K001926

Device Name: The *Vectra*™ Tunneler

Indications For Use: The *Vectra*™ Tunneler is indicated for use in creating subcutaneous tunnels for the placement of the Thoratec *Vectra*™ VAG for arteriovenous access.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K001926

Prescription Use√ OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)